Assembly Bill No. 1709

CHAPTER 235

An act to amend Sections 9203, 9211, 9212, 9221, 9231, 9241, 9242, 9244, 9245, 9251, 9261, 9263, 9264, 9267, and 9268 of, to amend the heading of Chapter 1.5 (commencing with Section 9201) of Part 1 of Division 5 of, to amend the heading of Article 5 (commencing with Section 9241) of Chapter 1.5 of Part 1 of Division 5 of, to add Section 9210 to, to add the heading of Article 2 (commencing with Section 9210) to Chapter 1.5 of Part 1 of Division 5 of, to add, amend, and renumber Section 9204 of, to repeal Section 9243 of, to repeal the heading of Article 2 (commencing with Section 9211) of Chapter 1.5 of Part 1 of Division 5 of, and to repeal and add Section 9205 of, the Food and Agricultural Code, relating to biologics.

[Approved by Governor September 23, 2010. Filed with Secretary of State September 24, 2010.]

LEGISLATIVE COUNSEL'S DIGEST

AB 1709, Conway. Biologics: animal blood and blood component products: commercial blood banks for animals.

Existing law defines biologics, requires the Secretary of Food and Agriculture to license biologic establishments that meet specified requirements, provides requirements relating to the application for a biologic license, and requires a certain biologic license application fee and license renewal fee. A violation of these provisions is a crime.

This bill would revise the definition of biologics, prohibit a person from engaging in the production of animal blood and blood component products, as defined, for retail sale and distribution except in a commercial blood bank for animals, as defined, licensed by the secretary, delete the requirement that the secretary license biologic establishments and instead require the secretary to license commercial blood banks for animals that meet specified requirements, and revise the license application provisions and license application fee and renewal fee provisions to instead make them applicable to producers of animal blood and blood component products. Because this bill would change the definition of an existing crime and create new crimes, the bill would impose a state-mandated local program.

Existing law prohibits a person from engaging in the production of biologics except in an establishment licensed by the United States Department of Agriculture or the Secretary of Food and Agriculture or in an establishment producing biologics only for use by the owner or operator for animals owned by him or her.

This bill would instead prohibit a person from engaging in the production of biologics except as permitted under federal law.

Existing law prohibits the offer for sale or use of any biologic unless it is registered by the secretary, except that registration is not required of any biologic manufactured pursuant to the terms of a valid license issued by the United States Department of Agriculture unless the secretary finds that, due to local conditions, it is necessary that the biologic be registered.

This bill would, instead, prohibit the offer for sale or use of any biologic unless it is manufactured pursuant to the terms of a valid license or permit issued by the United States Department of Agriculture. The bill would also prohibit the offer for sale or use of any blood or blood component product unless it is produced in an establishment licensed by the secretary, thereby imposing a state-mandated local program by creating a new crime.

Existing law requires the secretary to register any biologic that meets certain requirements and a biologic that is produced in an establishment exempt from licensing and that meets certain requirements, provides requirements relating to the application for registration of a biologic, and authorizes the secretary to impose conditions on the production or use of biologics.

This bill would delete the requirement that the secretary register biologics and instead require the secretary to register blood or blood component products that meet certain requirements. The bill would also require an application for registration of blood or blood component products to include specified information and would authorize the secretary to impose conditions on the production or use of blood or blood component products.

Existing law provides various enforcement provisions that the secretary may undertake with respect to biologic licensees and registrants.

This bill would revise those enforcement provisions to instead make them applicable to commercial blood banks for animals licensees and registrants of blood or blood component products.

This bill would make other conforming, clarifying, and technical changes.

This bill would state that its provisions are declaratory of existing law as applied to commercial blood banks for animals.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

This bill would provide that its provisions shall not become operative until the first day on or after January 1, 2013, that all Californiabiological products registered with the Department of Food and Agriculture by December 31, 2010, have obtained a United States Veterinary Biological Product License from the United States Department of Agriculture Center for Veterinary Biologics except those products for which the Department of Food and Agriculture has received written documentation from a firm that the firm has chosen not to obtain that license. The bill would require the Department of Food and Agriculture to assist, as provided, toward federal biological products licensure. The bill would also require the Department of Food and Agriculture to submit a report to the Legislature on the status

of biologics transitioning to federal biological products licensure by June 1, 2011, and every June thereafter until this act becomes operative and, when it does become operative, to post that fact on its Internet Web site.

The people of the State of California do enact as follows:

SECTION 1. The heading of Chapter 1.5 (commencing with Section 9201) of Part 1 of Division 5 of the Food and Agricultural Code is amended to read:

CHAPTER 1.5. COMMERCIAL BLOOD BANKS FOR ANIMALS AND BIOLOGICS

SEC. 2. Section 9203 of the Food and Agricultural Code is amended to read:

9203. "Biologics" means all viruses, serums, antibody products, toxins (excluding substances that are selectively toxic to microorganisms, for example, antibiotics), or analogous products at any stage of production, shipment, distribution, or sale, which are intended for use in the treatment of animals and which act primarily through the direct stimulation, supplementation, enhancement, or modulation of the immune system or immune response.

SEC. 3. Section 9204 is added to the Food and Agricultural Code, to read:

9204. "Blood and blood component products" means whole blood collected directly from a donor animal for transfusion or the blood components for transfusion including packed red blood cells, platelet-rich plasma, platelet concentrates, fresh plasma, fresh frozen plasma, frozen plasma, cryoprecipitate, and cryosupernatant. Antibody products like hyperimmune serums are considered "biologics" and are excluded from this definition of blood and blood component products.

SEC. 4. Section 9204 of the Food and Agricultural Code is amended and renumbered to read:

9206. "Production" means collection of blood or the preparation, testing, processing, storage, or distribution of blood or blood component products for the purpose of transfusion.

SEC. 5. Section 9205 of the Food and Agricultural Code is repealed.

SEC. 6. Section 9205 is added to the Food and Agricultural Code, to read:

9205. "Commercial blood bank for animals" means an establishment that produces animal blood or blood component products to market and sell for use in the cure, mitigation, treatment, or prevention of injury or disease in animals.

SEC. 7. The heading of Article 2 (commencing with Section 9211) of Chapter 1.5 of Part 1 of Division 5 of the Food and Agricultural Code is repealed.

SEC. 8. The heading of Article 2 (commencing with Section 9210) is added to Chapter 1.5 of Part 1 of Division 5 of the Food and Agricultural Code, to read:

Article 2. Animal Blood and Blood Component Products Production and Biologics Production

SEC. 9. Section 9210 is added to the Food and Agricultural Code, to read:

9210. No person shall engage in the production of animal blood and blood component products for retail sale and distribution except in a commercial blood bank for animals licensed by the secretary.

SEC. 10. Section 9211 of the Food and Agricultural Code is amended to read:

9211. No person shall engage in the production of biologics except as permitted under federal law.

SEC. 11. Section 9212 of the Food and Agricultural Code is amended to read:

9212. The secretary shall license establishments as commercial blood banks for animals that meet all of the following:

(a) Operate under conditions, and use methods of production, to ensure that the animal blood and blood component products will not be contaminated, dangerous, or harmful.

(b) Produce animal blood and blood component products under the direct supervision of a person qualified in the field.

(c) Maintain onsite records containing information documenting how the animal was acquired and any history of blood draws or use of anesthesia on the animal.

SEC. 12. Section 9221 of the Food and Agricultural Code is amended to read:

9221. An application for a license for any establishment that produces, or proposes to produce, animal blood and blood component products shall be made on forms issued by the secretary. The application shall contain all of the following:

(a) The name and address of the person who owns the place, establishment, or institution in which it is proposed to produce animal blood and blood component products.

(b) The name and address of the person who shall be in charge of the production of animal blood and blood component products.

(c) The type of animal blood and blood component products that shall be produced.

(d) A full description of the building, including its location, facilities, equipment, and apparatus to be used in the production of animal blood and blood component products.

(e) A written protocol that addresses all of the following:

(1) Maximum length of time for donation by animal donors, or minimum health parameters for animal donors.

(2) Frequency and volume of blood collected from animal blood donors.

(3) Socialization and exercise programs for animal blood donors.

(4) Method of identification of each animal, including microchip or tattoo.

(5) Ongoing veterinary care, including an annual physical exam and vaccination schedule for animals held in blood donor facilities.

(6) Husbandry standards for feeding, watering, sanitation, housing, handling, and care in transit, with minimums based on the standards set forth pursuant to the federal Animal Welfare Act in Part 3 (commencing with Section 3.1) of Subchapter A of Chapter 1 of Title 9 of the Code of Federal Regulations.

(7) Implementation of a permissive adoption program.

(f) An "oversight letter" identifying the oversight veterinarian who will be responsible for oversight of the facility. The letter shall be from the oversight veterinarian, and shall be maintained on file by the secretary. Oversight veterinarians shall be licensed to practice veterinary medicine in California. In the event of a change of the oversight veterinarian, it is the oversight veterinarian's responsibility to give notice to the secretary of the termination of the oversight veterinarian within 30 days of the termination date of the oversight veterinarian. An oversight letter from the incoming oversight veterinarian shall be submitted to the secretary within 30 days of the termination date of the prior oversight veterinarian.

(g) Additional information that the secretary finds is necessary for the proper administration and enforcement of this chapter.

SEC. 13. Section 9231 of the Food and Agricultural Code is amended to read:

9231. The license application fee and license renewal fee under this chapter for an establishment proposing to produce or producing animal blood and blood component products shall be as follows:

(a) The application and annual license fee shall be two hundred fifty dollars ($250) for each establishment, which shall be the fee for the fiscal year, or portion thereof, ending June 30 of each year. When an applicant is a city, county, state, or district, or an official thereof, no fee shall be required under this section.

(b) Licenses shall be renewed every year. The annual renewal fee shall be paid on or before the first day of July of each year.

(c) Fees may be increased by the department to cover the department's reasonable costs incurred in connection with performing the annual inspection required by Sections 9266 and 9268.

(d) The fees required by this section are maximum, and may be fixed by the secretary at a lesser amount for any fiscal year whenever he or she finds that the cost of administering this chapter can be defrayed from revenues derived from the lower fees.

SEC. 14. The heading of Article 5 (commencing with Section 9241) of Chapter 1.5 of Part 1 of Division 5 of the Food and Agricultural Code is amended to read:

Article 5. Blood or Blood Component Product Registration

SEC. 15. Section 9241 of the Food and Agricultural Code is amended to read:

9241. No person shall offer for sale or use any of the following:

(a) Any biologic unless it is manufactured pursuant to the terms of a valid license or permit issued by the United States Department of Agriculture.

(b) Any blood or blood component product unless it is produced in an establishment licensed by the secretary.

SEC. 16. Section 9242 of the Food and Agricultural Code is amended to read:

9242. The secretary shall register blood or a blood component product that meets all of the following requirements:

(a) It is produced under acceptable procedures.

(b) It has been demonstrated to the secretary that the blood or blood component product is safe and noninjurious to animal health.

(c) It has been demonstrated to the secretary that the blood or blood component product is of value for the purpose intended.

(d) It is labeled for proper handling and use, and is not misrepresented.

(e) It is produced in an establishment that meets the requirements of Section 9210.

SEC. 17. Section 9243 of the Food and Agricultural Code is repealed.

SEC. 18. Section 9244 of the Food and Agricultural Code is amended to read:

9244. An application for registration of blood or a blood component product shall include both of the following:

(a) A protocol of the methods of production in detail that is followed in the production of the product.

(b) A sample of the label to be placed on the blood or blood component product.

SEC. 19. Section 9245 of the Food and Agricultural Code is amended to read:

9245. The secretary may impose such conditions on the production or use of blood or blood component products as he or she deems necessary to accomplish the purposes of this chapter.

SEC. 20. Section 9251 of the Food and Agricultural Code is amended to read:

9251. The secretary may adopt reasonably necessary rules and regulations for the administration and enforcement of this chapter.

SEC. 21. Section 9261 of the Food and Agricultural Code is amended to read:

9261. License for any commercial blood bank for animals or registration of any blood or blood component product may be denied, suspended, or revoked by the secretary for failure to meet the requirements of this chapter or for the violation of any provision of this chapter, or of any rule or regulation adopted by the secretary under this chapter. The proceedings

shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code.

SEC. 22. Section 9263 of the Food and Agricultural Code is amended to read:

9263. If the secretary finds that blood or blood component products do not conform to the requirements of Section 9242 or the use or continued use of such products constitutes an immediate danger to animals, the secretary may, after notice, suspend the registration of those blood or blood component products or license of an establishment producing those blood or blood component products pending a hearing and final decision.

SEC. 23. Section 9264 of the Food and Agricultural Code is amended to read:

9264. (a) If the secretary finds blood or blood component products that do not meet the requirements of Section 9242, the secretary may order those blood or blood component products to be held on the premises where found or elsewhere until he or she has determined that the products may be safely released for the purposes intended.

(b) The secretary may order the destruction of any blood or blood component products under a hold order if the blood or blood component products cannot be made to meet the requirements of Section 9242.

SEC. 24. Section 9267 of the Food and Agricultural Code is amended to read:

9267. Notwithstanding Section 4827 of the Business and Professions Code, for commercial blood banks for animals licensed by the department, anesthesia shall be performed pursuant to Section 4826 of the Business and Professions Code.

SEC. 25. Section 9268 of the Food and Agricultural Code is amended to read:

9268. The requirements set forth in subdivision (c) of Section 9212, subdivision (e) of Section 9221, subdivision (c) of Section 9231, and Sections 9266 and 9267:

(a) Shall not apply to those facilities required to be inspected by the United States Department of Agriculture in accordance with the Animal Welfare Act (Chapter 54 (commencing with Section 2131) of Title 7 of the United States Code).

(b) Shall apply to those facilities housing blood donor animals under contract with commercial blood banks for animals licensed by the department.

(c) Shall not apply to private veterinarians who maintain their own, in-office blood donor animals for use in their own practice.

SEC. 26. The Legislature finds and declares that the amendments made to Chapter 1.5 (commencing with Section 9201) of Part 1 of Division 5 of the Food and Agricultural Code by this act do not constitute a change in, but are declaratory of, existing law as applied to commercial blood banks for animals.

SEC. 27. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that

may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

SEC. 28. (a) To ensure uninterrupted availability of California-specific biological products, this act, except for subdivisions (b), (c), and (d) of this section, shall not become operative until the first day on or after January 1, 2013, that all California biological products, as defined in Section 101.2 of Title 9 of the Code of Federal Regulations, registered with the Department of Food and Agriculture by December 31, 2010, have obtained a United States Veterinary Biological Product License from the United States Department of Agriculture (USDA) Center for Veterinary Biologics except those products for which the Department of Food and Agriculture has received written documentation from a firm that the firm has chosen not to obtain that license. However, new registrations of biologics will not be processed by the Department of Food and Agriculture after December 31, 2010. When this act becomes operative, the Department of Food and Agriculture shall post that fact on its Internet Web site.

(b) It is the intent of the Legislature that the role of the Department of Food and Agriculture shall continue to be to advocate and interact with interested parties and the USDA Center for Veterinary Biologics to assist in the process for biologics of importance to California's livestock industry, and as defined in Sections 101.2 and 101.3 of Title 9 of the Code of Federal Regulations, to obtain a United States Veterinary Biological Product License.

(c) The Department of Food and Agriculture shall submit a report to the Legislature on the status of biologics transitioning to United States Veterinary Biological Product Licensure and of any additional products as described in subdivision (d) by June 1, 2011, and every June thereafter until this act becomes operative as set forth in subdivision (a).

(d) The Department of Food and Agriculture shall use its best efforts to immediately interact with the USDA Center for Veterinary Biologics to assist in the process for California biological products, as defined in Section 101.2 of Title 9 of the Code of Federal Regulations, registered with the Department of Food and Agriculture by December 31, 2010, to obtain a United States Veterinary Biological Product License. Upon request, the Department of Food and Agriculture shall assist research sponsors in obtaining the authorizations for shipment or delivery as an experimental biological product, according to Section 103.3 of Title 9 of the Code of Federal Regulations, for products currently under development to ensure ongoing progress toward obtaining a United States Veterinary Biological Product License.

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